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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,918	11/24/2003	Arnon Nagler	85189-5500	9844
28765	7590	01/28/2005	EXAMINER	
WINSTON & STRAWN PATENT DEPARTMENT 1400 L STREET, N.W. WASHINGTON, DC 20005-3502			HENLEY III, RAYMOND J	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 01/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/723,918	Applicant(s) NAGLER ET AL.	
	Examiner Raymond J Henley III	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-11 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-11 and 15-17 is/are rejected.
- 7) ☒ Claim(s) 9 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

CLAIMS 9-11 AND 15-17 ARE PRESENTED FOR EXAMINATION

Applicants' amendment filed December 20, 2004 has been received and entered into the application. Accordingly, claims 1-8 and 12-14 have been canceled; claim 9 has been amended; and claims 15-17 have been added.

In view of the amendments, the rejections of (i) claims 9-11 under 35 U.S.C. § 112, first paragraph; and (ii) claims 1-8 and 12-14 under 35 U.S.C. § 102(b) as being anticipated by Pines et al. (U.S. Patent No. 5,449,678), as set forth in the previous Office action dated August 18, 2004 at pages 2-4, are withdrawn.

Claim Objection

Claims 9 and 15 are objected to because of the following informalities:

In claim 9, "the subject in need thereof" (lines 3-4) does not have specific antecedent basis. The phrase should be rewritten as "a subject in need thereof" or "the subject".

In claim 15, lines 2-3, "said subject" does not have antecedent basis. At line 1, after "renal function", ---of a subject--- should be inserted.

Appropriate correction is required.

Claim Rejection - 35 USC § 103

Claims 9-11 and 15-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Pines et al. (U.S. Patent No. 5,449,678), already of record, for the reasons of record as set forth in the previous Office action dated August 18, 2004 at pages 4-6, as applied to claims 1-8 and 12-14 under 35 U.S.C. § 102(b) and to claims 3, 7, 8 and 14 under 35 U.S.C. § 103(a).

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Applicants' arguments at pages 5-6 of the amendment have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

Applicant's arguments, i.e., "[t]he amendments presented herein place the application in condition for allowance." (amendment at page 6, third paragraph), fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Pines et al. would have suggested the newly added claim requirements for "attenuating the progression of renal fibrosis in a subject exposed to an inducer of renal fibrosis" (claim 9 at lines 1-3); "the step of administering is performed before the subject exhibits renal fibrotic condition" (claim 9, penultimate and last line); and "[a] method for preserving renal function following exposure to an inducer of renal fibrosis" (claim 15, lines 1-2).

In particular, Pines et al. would have suggested that the progression of renal fibrosis could be attenuated because the patentees teach that "[i]t is generally recognized that at present, most treatments of fibrotic diseases are ineffective and have little effect on their inexorable pathological progression" (col. 1, lines 55-57) and further teach that by practicing their invention, a treatment of fibrotic diseases may be accomplished, i.e., "it has now been discovered that halofuginone, on the other hand, is a specific $\alpha 1$ type I collagen synthesis inhibitor...[which] decreased the fibrosis by decreasing collagen type I synthesis.." (col. 2, lines 37-47), and that "the other quinazolinone derivatives...have similar properties (col. 2, lines 48-51).

Also, Pines et al. would have suggested that renal fibrosis in a patient subjected to a renal fibrosis inducer could be attenuated because the patentees highlight that the fibrotic conditions

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may be conditions caused by other pathological conditions, i.e., inducers. Thus, at col. 3, lines 42-44, Pines et al. teach “[f]ibrotic processes are the primary cause or the end result of the healing process of multiple inflammatory, physical injuries and autoimmune disorders, as well as aging.”.

The claim requirement of “preserving renal function following exposure to an inducer of renal fibrosis” (claim 15) is provided for at col. 1, lines 59-63 where the patentees teach “[a]s is known, progressive fibro- proliferative diseases exhibit excessive production of connective tissues, which results in destruction of normal tissue architecture *and function*.” (emphasis added).

Finally, while Pines et al. fails to expressly disclose the treatment of a patient subjected to a renal fibrosis inducer who is not exhibiting a renal fibrotic condition, it is believed that such a concept would have been appreciated as being within the spirit or essential attributes of the invention of Pines et al. Such is believed to be the case because it would have been recognized by one of ordinary skill in the art that a patient suffering from a condition such as an autoimmune disorder would be at risk for developing renal fibrosis (see above and the previous Office action). One of ordinary skill in the art would have been concerned with maintaining the health of the patient to the greatest extent possible and thus would have been motivated to inhibit the development of *any* pathological sequela of an autoimmune disease, such a renal fibrosis, of which he or she would have been aware.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

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Applicants' amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond A. Henley III
Primary Examiner
Art Unit 1614

January 26, 2005